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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/121,849	07/24/98	GARFIELD	SCH1237DI

*KM*

023599 HM12/0501  
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EXAMINER LILLING, H
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ART UNIT 1651	PAPER NUMBER
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DATE MAILED: 05/01/01 *Lo.*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/121,849

Applicant(s)

GARFIELD ET AL

Examiner  
DR. HERBERT J. LILLING

Art Unit  
1651



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32-35 is/are pending in the application.
- 4a) Of the above, claim(s) 1-13, 15, 16, 20-27, 30, and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 17-19, 28, and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-13, 15, 16, 20-27, 30, and 32-35 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

1. Receipt is acknowledged of the election filed April 03, 2001.

2. Claims 1-30 and 32-35 remain present in the instant application. Claim 31 has been cancelled.

3. Applicant has elected Group II, Claims 14, 17, 18, 19, 28 and 29, drawn to a pharmaceutical composition containing at least the following three components (a) a progestin and the species , **progesterone** (b) a nitric oxide synthesis substrate, a nitric oxide donor or both, the elected species is **a nitric acid donor which species is nitroglycerin** and (c) at least one of the ingredients as noted by Claim 14, and (c) **is a cyclooxygenase inhibitor which is aspirin.**

Claims 1-13, 15, 16, 20, 21, 22-27, 30, 32-33 and 34-35 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions or species.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

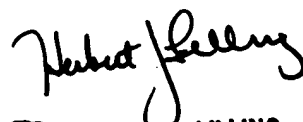
Claim 14, 17, 18, 19, 28 and 29 are rejected under 35 U.S.C. 103(a) as obvious over Harrison et al U.S. 5,508,045.

Harrison et al teaches in columns 21-22 and examples compositions which specifically teaches processes which employs obvious compositions of nitroglycerin in combination with nitric oxide donors, see column 35 as well as employing the elected species aspirin.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL  
(703) 308-2034  
Art Unit 1651  
April 30, 2001

  
HERBERT J. LILLING  
PATENT EXAMINER  
GROUP 1800 ART UNIT 1651